

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 29D0652730	(X3) Date Survey Completed 04/08/2021
Name of Provider or Supplier Mt Grant General Hospital Laboratory	Street Address, City, State 200 South A Street, Hawthorne, NV	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	<p>This Statement of Deficiencies was created as a result of an on-site CLIA recertification survey conducted at your facility on 4/08/2021. The findings and conclusions of any investigation by the Division of Public and Behavioral Health shall not be construed as prohibiting any criminal or civil investigations, actions or other claims for relief that may be available to any party under applicable federal, state, or local laws.</p>
D3000	<p>FACILITY ADMINISTRATION CFR(s): 493.1100</p> <p>Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe.</p> <p>This CONDITION is not met as evidenced by: Based on a sample survey of the laboratory test worksheet for manual tests, review of the copy machine's number of fax transmission confirmations from 2/01/2021 through 2/08/2021, and interview with the technical supervisor, the Condition: Facility Administration was not met. The laboratory failed to report SARS-CoV-2 (COVID-19) test results as required for tests performed from 2/01/2021 through 2/08/2021. Findings include: 1. The laboratory began SARS-CoV-2 testing using the BinaxNow Rapid COVID-19 Antigen Card Test in 9/2020 and began reporting the test results to the authority by fax transmission. 2. A sample survey of the laboratory test worksheets for SARS-CoV-2 (COVID-19) reviewed from 2/01/2021 through 2/08</p>

/2021 revealed that the laboratory performed 107 SARS-CoV-2 tests during the time period. 3. Review of the copy machine's log of the number of fax transmission confirmations for 2/01/2021 through 2/08/2021 to the authority's fax number revealed that the number of tests performed and the number of results reported to the authority did not match for the time period. DATE TESTED FAXED 2/1/2021 24 0 2/2/2021 23 25 2/3/2021 26 25 2/4/2021 5 12 2/5/2021 1 0 2/6/2021 2 0 2/7/2021 1 0 2/8/2021 25 35 total 107 97 4. The technical supervisor interviewed during the on-site inspection on 4/08/2021 at approximately 4:00 PM indicated that the laboratory did not confirm that all the tests performed were reported to the reporting authority. The technical supervisor stated that the laboratory performs approximately 100 SARS-CoV-2 tests monthly.

D5449

CONTROL PROCEDURES
CFR(s): 493.1256(d)(3)(ii)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on review of laboratory procedures for the serum pregnancy and infectious mononucleosis, review of the quality control logs for the two tests, review of the Daily Order Log, and interview with the technical supervisor, the laboratory failed to test a negative and positive control at least once a day patient specimens were tested. Findings include: 1. Laboratory procedure, HCG by SUREVUE, stated, "Known positive and Negative controls are run each day of shipment, new Lot and/or at least once a month." 2. Laboratory procedure, Infectious Mononucleosis by Acceava Mono II stated, "External Positive and Negative controls are run each new lot, new shipment and/or at least once a month." 3. Review of the quality control logs for the SURE-VUE Serum/Urine hCG-STAT and the Infectious Mononucleosis by Acceava Mono II for January to April 2021 revealed that quality control testing with negative and positive control materials was performed once a month. 4. Review of the Daily Order Log revealed a qualitative serum pregnancy (HCG) test performed on 3/11/2021. The quality control was performed on 3/01/2021 for the current lot number of tests in use. 5. The technical supervisor interviewed during the on-site survey on 4/08/2021 at approximately 3:00 PM indicated that the negative and positive controls were not tested each day of patient testing. The laboratory performs approximately 365,00 chemistry and 200 general immunology tests annually.

D5537

ROUTINE CHEMISTRY
CFR(s): 493.1267(b)(d)

For blood gas analyses, the laboratory must perform the following: (b) Test one sample of control material each 8 hours of testing using a combination of control materials that include both low and high values on each day of testing. (d) Document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:
Based on review of the epoc System Manual for blood gas analysis and interview with

the technical supervisor, the laboratory failed to perform a low and high control testing each day of patient testing. Findings include: 1. The epoc System Manual for blood gas analysis in section 9.2 Recommended Quality Control for epoc System stated, "Follow federal, state, and local requirements for quality control testing." 2. The technical supervisor interviewed during the on-site survey on 4/08/2021 at approximately 11:00 AM indicated that external quality controls were tested with each new lot number of test cartridges and once per month. The laboratory did not test two levels of quality control each day of patient testing. The laboratory performs approximately 365,000 chemistry tests annually.

D6040

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(2)

The technical consultant is responsible for-- (b)(2) Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system.

This STANDARD is not met as evidenced by:
Based on review of the epoc Correlation Studies with the Istat instrument and interview with the technical consultant and the technical supervisor, the technical consultant failed to follow the laboratory procedure for the verification of the epoc System for blood gas analysis. Findings include: 1. During an interview with the technical consultant during the on-site survey on 4/08/2021 at approximately 11:00 AM, the technical consultant indicated that the number of samples to be evaluated for the correlation studies to verify the performance specifications for new instruments was 20 and indicated procedure, Laboratory Quality Management, Inter-Instrument Correlation as the source of the number of samples. 2. Laboratory procedure, Laboratory Quality Management, Section Inter-Instrument Correlation, stated, "A random sampling of at least 20 patient samples for all routine analytes and tests are tested on both instruments and the results recorded on the appropriate worksheets." 3. Review of the epoc Correlation Studies for the new blood gas analysis instrument showed 18 samples for carbon dioxide and 19 samples for pH and oxygen were evaluated for the studies. 4.. The technical supervisor interviewed during the on-site survey on 4/08/2021 at approximately 11:00 AM indicated that there were other patient samples tested in parallel on the epoc System and the Istat instrument but did not document the findings. The laboratory performs approximately 365,000 chemistry tests annually.